IgE-CHECK-1

Quantitative determination of immunoglobulin-E in whole blood, plasma or serum samples

Ref. 18091

FOR EASY READER® AND EASY READER® + USE ONLY

I- PRINCIPLE

Immunoglobulin E (IgE) is an immunoglobulin normally found in nanogram level in healthy individual (1, 2).
In allergic patients, IgE is present both in the serum and also tightly bound to the surface of basophils and mast cells (3, 4). Screening the level of total IgE is of diagnostic use in case of asthma (to differentiate allergic from non allergic asthma), rhinitis and eczema (5).
Other diseases in which elevated levels of serum IgE are found include parasitic infections, broncho-pulmonary aspergillosis and some dermatitis.
The IgE-CHECK-1 is a rapid quantitative assay for the detection of IgE in whole blood, plasma or serum samples. The method employs a unique combination of monoclonal dye conjugate and polyclonal solid phase antibodies to identify IgE in the test samples with a high degree of sensitivity.
As the test sample flows through the absorbent device, the antibody-dye conjugate binds to the IgE forming an antibody-antigen complex. This complex binds to the anti IgE antibody in the reaction zone (T) and produces a pink-rose colour band. In absence of IgE, the mixture continues flowing through the absorbent device past the reactive zone (T) and control zone (C). Unbound conjugate binds to the reagents in the control zone (C), producing a pink-rose colour band, demonstrating that the reagents are functioning correctly.

II- IgE-CHECK-1 KIT COMPONENTS

Each kit contains everything needed to perform 10 or 20 tests:

1- IgE-CHECK-1 test devices	10	20
2- Disposable plastic pipettes	10	20
3- Diluent in a dropper bottle	2.5mL	5mL
4- Instruction leaflet	1	1

5- **Controls** (**Optional):**
Positive control ref. V1890 and Negative control ref. V1891: a freeze-dried preparation of a non-infectious compound in diluted human serum, tested and found negative for anti-HIV, anti-HCV and HBs antigen, containing 0.05 % sodium azide is optionally available as a positive and negative control (1x 0.25 mL). The concentration range is indicated on the vial label.

III- STORAGE AND STABILITY

1- All IgE-CHECK-1 kit components, including optional control before reconstitution, should be stored at any temperature between +4°C and +30°C in their original package.
2- ***Do not freeze the test kit.***
3- The IgE-CHECK-1 kit is stable until the expiry date stated on the package label.

IV- PRECAUTIONS

1- This test is designed for *in vitro* diagnostic use and professional use only.
2- Read carefully the instructions before using this test.
3- Handle all specimens as if they contained infectious agents. When the assay procedure is completed, dispose of specimens carefully after autoclaving them for at least one hour. Alternatively, they can be treated with 0.5% to 1% solution of sodium hypochlorite for one hour before disposal.
4- Wear protective clothing such as laboratory coats and disposable gloves while assaying samples.
5- Do not eat, drink or smoke in the area where specimens and kit reagents are handled.
6- Avoid any contact between hands and eyes or nose during specimen collection and testing.
7- Do not use beyond the expiry date which appears on the package label.
8- Do not use a test from a damaged protective wrapper.

V- SPECIMEN COLLECTION AND PREPARATION

1- IgE-CHECK-1 rapid test is performed on human serum, plasma or whole blood.
2- The specimen should be collected under the standard laboratory conditions (aseptically in such a way as to avoid haemolysis)
3- If anticoagulant is needed, only citrate, EDTA or heparin should be used.
4- Each specimen should be treated as if potentially infectious.
5- Whole blood samples should be tested immediately (< 4 hours). Finger prick samples should be assayed just after collection.
6- If the test is to be run within 48 hours after collection the specimen should be stored in the refrigerator (+2°C to +8°C). If testing is delayed more than 48 hours, the specimen should be frozen. The frozen specimen must be completely thawed, thoroughly mixed and brought to room temperature prior to testing. Avoid repeated freezing and thawing.
7- In case of cloudiness, high viscosity or presence of particulate matter into the serum specimen, it should be diluted with equal volume (V/V) of diluting buffer (not provided but available upon request) before testing.

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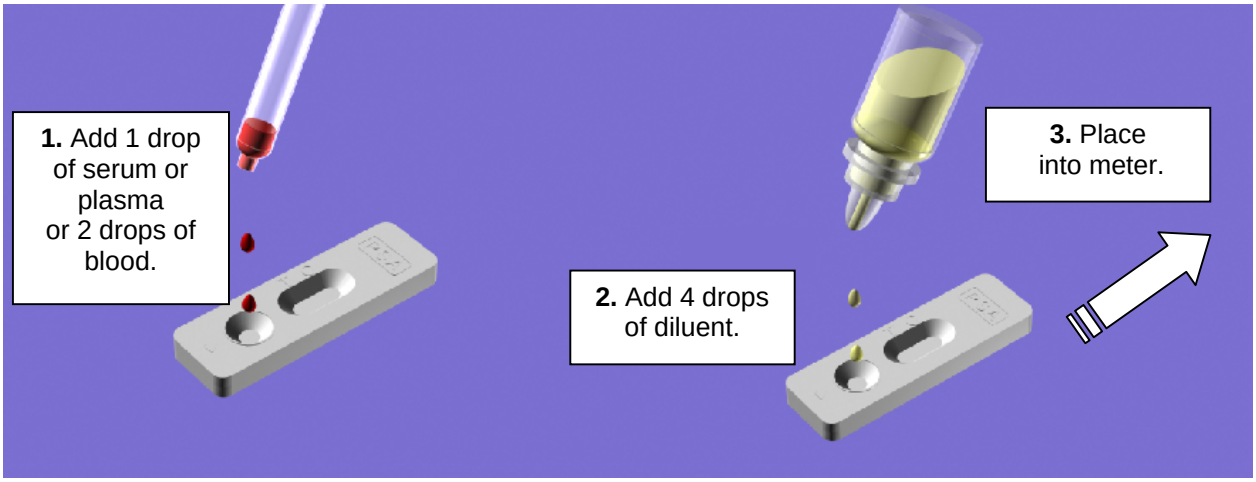
b) Samples testing

Follow the instructions below or refer to the picture n°1.

1- Allow the sample and IgE-CHECK-1 test device to return to room temperature prior to testing.
2- Remove the reaction device from its protective wrapper by tearing along the line.
3- Label the device with the patient's name or control number.
4- Fill the serum dropper with specimen (serum or plasma) and by holding it vertically, dispense one drop (25 µL) into sample well. (If whole blood is used, dispense 2 drops (50 µL) into the well (▷) **and wait for the blood sample to be completely absorbed before adding diluent**.
5- Add exactly 4 drops of diluent (150 µL) in the sample well (▷).
6- Read the result **(in IU/mL)** after 10 minutes either using the immediate or countdown reading mode (see corresponding lealfet).

For general instructions describing how to use the VEDALAB rapid test readers, refer to the corresponding leaflet.



Picture n° 1

VII- PERFORMANCES CHARACTERISTICS

a) Linearity

The measuring range is 10 - 800 IU/mL.
For IgE concentration below 10 IU/mL, the result will be given as "< 10 IU/mL".
For IgE concentration over 800 IU/mL, the result will be given as "> 800 IU/mL".
For samples whose concentration is higher than 800 ng/mL, dilute with saline and repeat the assay as per instructions of Part. VI.

b) Sensitivity

The test sensitivity has been adjusted to 10 IU/mL using the second WHO IgE international standard 75/502. However concentrations close to 5 IU/mL are detected by IgE-CHECK-1 test. In these cases, results will be rendered as "< 10 IU/mL".

IgE concentrations higher than 150 IU/mL are generally considered as abnormal.

c) Accuracy

A study has been performed using serum samples obtained from dilutions of the IgE international standard 75/502 (W.H.O.) covering a range of 0 to 800 IU/mL.

Optical densities expressed as a function of IgE concentrations are described by following polynomial curve:

$$Y = 49.94 + 1.567\ X - 1.201.10^{-3}\ X^2\ (r = 0.93)$$

The results show a good correlation (r > 0.90) of the values obtained with IgE-CHECK-1 on VEDALAB's readers.

d) Precision

A study was performed on 22 human sera preassayed on PHARMACIA analyser. The results have been read with the VEDALAB's readers.

The results are summarized in table I.

Human sera Identification	[IgE] in IU/mL Expected values (PHARMACIA)	Confidence range		[IgE] in IU/mL Obtained values (IgE-CHECK-1)
		Lower Limit	Upper limit	
1	3	2.4	3.6	<10
2	6	4.8	7.2	<10
3	8	6.4	9.6	<10
4	10	8	12	<10
5	1*	0.8	1.2	<10
6	50	40	60	46.45
7	52	41.6	62.4	54.66
8	55.2	44.16	66.24	46.74
9	55.2	44.16	66.24	55.88
10	72	57.6	86.4	84.07
11	143*	114.4	171.6	161.45
12	120	96	144	104.26
13	123	98.4	147.6	121.31
14	135	108	162	153.27
15	160	128	192	147.94
16	178	142.4	213.6	212.93
17	179	143.2	214.8	182.03
18	322	257.6	386.4	290.09
19	424	339.2	508.8	467.85
20	461	368.8	553.2	380.86
21	**582**	**465.6**	**698.4**	**428.14**
22	**615**	**492**	**738**	**401.66**

Table I: Comparison between IgE-CHECK-1 and Pharmacia

From the above table, a discrepancy is obtained with serum n°21 and serum n°22: the results by the both methods indicates probably the same clinical diagnosis profile.
Negative, borderline and positive samples are correctly detected (a correlation of 95.4% is obtained between VEDALAB IgE-CHECK-1 and Pharmacia IgE test.

e) Hook effect
There was no observed hook effect up to an IgE concentration of 32,000 IU/mL.

f) Interference
No reaction was observed with critical RF and complement interfering sera.

g) Intra-assay reproducibility
Within run precision was evaluated by using 26 replicates of two commercially available sera containing 283.15 and 124.50 IU/mL of IgE as determined with quantitative IgE-CHECK-1 for VEDALAB's readers.
The obtained CV (coefficient of variation) were respectively equal to 9.76 % and 9.81 %.

VIII-LIMITATIONS

1- The 10 IU/mL version of IgE-CHECK-1 test is specifically designed to detect IgE in whole blood, plasma and serum samples.
2- As for any diagnostic procedure, the physician should evaluate data obtained by the use of this kit in light of other clinical information.
3- **Use only fresh whole blood samples (< 4 hours) when test is performed with blood samples. Finger prick samples should be assayed just after collection.**
4- In case of high RF (rheumatoid factor) or CRP (C-reactive protein) concentrations (high levels indicate acute infections), the test could exceptionally show a positive result.
5- The test is designed to eliminate the potential interference of human antibodies to murine IgG (HAMA). However, high level of HAMA could give falsely positive results.
6- This format of test is to be only used with VEDALAB's rapid test readers (EASY READER® or EASY READER+®).
7- If the reading time (10 minutes) is not strictly respected, wrong results will be obtained.
8- The 10 IU/mL IgE-CHECK-1 should not be used for visual reading.
9- As for any diagnostic method or for any measurements through analysers, there is a variability of the obtained result. Therefore, a confidence range of +/-25% should be considered for the final value and for the clinical significance of the result.

IX- BIBLIOGRAPHY

1- Barbee R. A, M. Halonen, M. Lebowitz, and B. Burrows. 1981. Distribution of IgE in a community population sample; correlations with age, sex, and allergen skin test reactivity. J. Allergen Clin. Immunol. **68**: 106-111.
2- Kjellman, N-I.M, S.G.O. Johansson, and A. Roth. 1976. Serum IgE levels in healthy children quantified by a sandwich technique (PRIST). Clin. Allergy **6**: 51-59.
3- Ishika, T (1982), IgE and Mechanisms of IgE-mediated hypersensitivity, *Ann Allergy* **46**, 313-319.
4- Geha, RS (1984), Human IgE, *J Allergy & Clin Immunol*, 74, 109-120.
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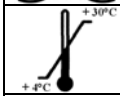
	Read the instructions before use		For *in vitro* diagnostic use
	Temperature limitations		Do not reuse
	Manufacturer		

Manufactured by VEDALAB - France